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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,937	07/24/2003	Michael Lebner	0156-2004US01	9900

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EXAMINER

EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3773

MAIL DATE	DELIVERY MODE
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08/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/625,937

Applicant(s)

LEBNER, MICHAEL

Examiner

Darwin P. Erez

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-18 and 20-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-18 and 20-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Art Unit: 3773

DETAILED ACTION

1. The Office action is in response to the communication filed on 5/8/08.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 3, 5, 10, 12, 15, 18, 20, 22, 27, 29, 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,531,521 to Haverstock in view of US 2,762,371 to Guio.

(claim 1) Fig. 6 of Haverstock discloses a two-component device for closing a laceration or incision, comprising:

a first component comprising a first adhesive-backed anchoring member **52** and first connecting members **58,60** extending from one edge thereof in a first direction, the first connecting members having a width that is substantially greater than their thickness;

Art Unit: 3773

a second component which is separate and distinct from the first component, the second component comprising a second adhesive-backed anchoring member **54** and second connecting members **62,64** extending from one edge thereof in a second direction, the second connecting members having a width that is substantially greater than their thickness; and

adhesives **68** for attaching the first connecting members to the second adhesive-backed anchoring member and for attaching the second connecting members to the first adhesive-backed anchoring member, the attachment of the one or more first and second connecting members to the first and second adhesive-backed anchoring members form attached and bridging portions of the one or more first and second connecting members, such that the attached portions are attached to the first and second adhesive-backed anchoring members, and the bridging portions span over the laceration area between the first and second adhesive-backed anchoring members (col. 7, ll. 50-68), wherein the adhesive is applied to at least a portion of a lower surface of the first and second connecting members (see cross-section shown in Fig. 7).

Haverstock is silent with regards to the bridging portions being substantially free of adhesive.

However, Guio discloses a similar type of wound closure device, the device having a first and second components; wherein the device is used to draw the edges of the wound together. The first and second components each have a bridging portion that spans over the wound site, wherein said bridging portion is substantially free of

Art Unit: 3773

adhesive. Instead, the bridging portion includes pad **30** to prevent the closure device from sticking to the wound.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the bridging portion of Haverstock to include the pad instead of adhesive because it would prevent the wound closure device from sticking to the wound as the edges of the wound are drawn together.

(claims 3 and 5) The unattached end portions of the first and second connecting members are viewed as the pulling elements, which are fully capable of being cut and removed.

(claims 10 and 12) The first and second connecting members are protected by a release liner that is separate from the release liner that protects the first and second anchoring member. As seen in Fig. 8, perforation **120** separates the release liners.

(claim 15) The edge of either component would serve as an alignment indicator relative to the wound or incision cut.

(claim 18) The above combination of Haverstock/Guio discloses the step of providing the device recited in claim 1, and wherein the first and second components are placed on opposite sides of a wound, and wherein the first and second connecting members extend over the wound to draw the edges of the wound together.

(claims 20 and 22) see the rejections to claims 3 and 5.

(claims 27 and 29) see the rejections to claims 10 and 12.

(claim 32) see the rejections to claim 15.

Art Unit: 3773

5. Claims 4, 6-9, 16, 17, 21, 23-26, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haverstock in view Guio and in further view of US 6,329,564 to Lebner.

The above combination Haverstock and Guio teaches all the limitations of the claim except for a coding means comprising an observable geometric distinction between the shape of the pulling elements and the shape of the anchoring members, that the coding comprises printed indicia enabling user distinction between pulling elements and anchoring members, that the coding further comprises distinguishing colors. The above combination is also silent with regards to the release liners recited in the claims and the type of material used to form the device.

(claims 4, 6-8, 21 and 23-25) Lebner teaches a wound closure device that can include wound visual alignment indicators, and further discloses at col. 5, lines 1-21, that the bandage can include indicia (e.g. color, graphic representation, etc.) for the purpose of indicating specific information to the user (e.g. tension).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to provide any portion of the device of Haverstock/Guio with indicia of various types (such as recited above) in order to indicate any information to the user. As such, the claims are not distinguishable from the prior art.

(claims 9 and 26) Lebner teaches a wound bandage formed from vapor-permeable material (col. 3, lines 5-15). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the device of

Art Unit: 3773

Haverstock/Guio with a vapor permeable material, as taught by Lebner, because it would allow for the exchange of air with the skin beneath the bandage.

(claims 16, 17, 33 and 34) The applicant does not clearly state what constitutes as a pull bar or wound edge bar. However, it is noted that Lebner teaches reinforcements for the device at col. 2, line 60 – col. 3, line 4. Therefore, it would be obvious to one of ordinary skill in the art to use reinforcements in the device of Haverstock/Guio because the reinforcements would help maintain the orientation of the device when tension is applied.

6. Claims 11, 13, 14, 28, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haverstock in view Guio and in further view of US 6,043,406 to Sessions et al.

The above combination of Haverstock and Guio teaches the device being protected by release liners but is silent with the release liners having coding to indicate sequence of removal. However, the use of color coded indicia is well known in the wound dressing art. As disclosed by Sessions, "indicia is useful for marking on the two tab system (which is part of the protective liners) that allow the error free application of [a] wound dressing' (col. 7, ll. 3-24). Thus, color or printed coding is used to determine the order of use for the device.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide color coded indicia to the protective covers of Haverstock/Guio because it would allow a practitioner to visually determine the order of use for the device, as disclosed by Sessions.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 18 and 20-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/626785 and in view of US 2,762,371 to Guio. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application only lacks the bridging portion lacking adhesive. However, as noted above, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the bridging portion of the copending application to include the pad instead of adhesive because it would prevent the wound closure device from sticking to the wound as the edges of the wound are drawn together.

Art Unit: 3773

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1, 3-18 and 20-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/626783 and in view of US 2,762,371 to Guio. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application only lacks the bridging portion lacking adhesive. However, as noted above, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the bridging portion of the copending application to include the pad instead of adhesive because it would prevent the wound closure device from sticking to the wound as the edges of the wound are drawn together.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1, 3-18 and 20-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/626040 and in view of US 2,762,371 to Guio. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application only lacks the bridging portion lacking adhesive. However, as noted above, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the bridging portion of the copending application to include the pad instead of adhesive because it would prevent the wound

Art Unit: 3773

closure device from sticking to the wound as the edges of the wound are drawn together.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 1, 3-18 and 20-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/625936 and in view of US 2,762,371 to Guio. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application only lacks the bridging portion lacking adhesive. However, as noted above, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the bridging portion of the copending application to include the pad instead of adhesive because it would prevent the wound closure device from sticking to the wound as the edges of the wound are drawn together.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Amendment/Arguments

12. The amendment to claims 11, 13, 14, 28, 30 and 31 have overcome the rejections under 35 U.S.C. 112, second paragraph.

13. Applicant's arguments filed 5/8/08 have been fully considered but they are not persuasive.

Art Unit: 3773

The applicant's main argument is with regards to the Haverstock reference allegedly failing to teach a bridging portion and connecting members. However, this is not persuasive because Haverstock discloses a device having anchoring members (52, 54) and connecting members (58, 60, 62, 64) extending from said anchoring members. The argument that the device of Haverstock is configured as "folded back portions" is not persuasive because in use, the connecting members (58, 60, 62, 64) do extend from the anchoring members.

It was also argued that the this connecting members do not form a bridging portion. This is not persuasive because the device of Haverstock is fully capable of being manipulated to have bridging portions. It is noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The device of Haverstock has connecting members (58, 60, 62, 64) that extend from their respective anchoring members and is fully capable of being configured to span over a laceration to form a bridging portion

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

Art Unit: 3773

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezzo/
Primary Examiner, Art Unit 3773